

**IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF VIRGINIA
Abingdon Division**

[UNDER SEAL],

SEALED

Relator-Plaintiff,

SECOND AMENDED COMPLAINT

v.

CASE NO.: 1:13cv00036

[UNDER SEAL]

FILED UNDER SEAL

Defendants.

31 U.S.C. Sec. 3730 (b)(2) & (3)

CLERK'S OFFICE U.S. DIST. COURT
AT ABINGDON, VA
FILED

DEC 14 2016

SEALED

JULIA C. DUDLEY, CLERK
BY: *[Signature]*
DEPUTY CLERK

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**UNITED STATES OF AMERICA and the
COMMONWEALTH OF VIRGINIA, the
COMMONWEALTH OF
MASSACHUSETTS, the States of
CALIFORNIA, COLORADO,
CONNECTICUT, DELAWARE,
FLORIDA, GEORGIA, HAWAII,
ILLINOIS, INDIANA, IOWA,
LOUISIANA, MARYLAND, MICHIGAN,
MINNESOTA, MONTANA, NEVADA,
NEW HAMPSHIRE, NEW JERSEY, NEW
MEXICO, NEW YORK, NORTH
CAROLINA, OKLAHOMA, RHODE
ISLAND, TENNESSEE, TEXAS,
VERMONT, WASHINGTON,
WISCONSIN, the DISTRICT OF
COLUMBIA, the CITY of CHICAGO, the
CITY of NEW YORK, the CALIFORNIA
DEPARTMENT of INSURANCE and the
ILLINOIS DEPARTMENT of
INSURANCE**

***TO BE FILED IN CAMERA AND
UNDER SEAL PURSUANT TO
31 U.S.C. §3730(b)(2)***

CASE NO.: 1:13cv00036

**Do Not Place in Press Box or Enter on
Publicly Accessible System (PACER)**

JURY TRIAL DEMANDED

***ex rel* ANN MARIE WILLIAMS
3208 St. Stephens Way
Midlothian, VA 23113**

Relator-Plaintiff,

v.

**RECKITT BENCKISER, INC.
Morris Corporate Center IV
399 Interpace Parkway
Parsippany, New Jersey 07054**

and

**RECKITT BENCKISER, LLC
Morris Corporate Center IV
399 Interpace Parkway
Parsippany, New Jersey 07054**

and

**RECKITT BENCKISER
PHARMACEUTICALS, INC.
10710 Midlothian Turnpike, Suite 430,
Richmond, Virginia 23235**

and

**RECKITT BENCKISER HEALTHCARE
(UK) LTD.
Dansom Lane, Hull,
North Humberside
HU8 7DS, England**

and

**RECKITT BENCKISER GROUP, PLC,
103-105 Bath Road, Slough,
Berkshire, SL1 3UH, England**

and

**INDIVIOR, INC.
10710 Midlothian Turnpike, Suite 430
Richmond, Virginia 23235**

and

**INDIVIOR PLC,
103-105 Bath Road, Slough,
Berkshire, SL1 3UH, England**

and

**INDIVIOR UK LIMITED
103-105 Bath Road, Slough,
Berkshire, SL1 3UH, England**

Defendants.

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SECOND AMENDED COMPLAINT

Ann Marie Williams, by counsel, states as follows for her Second Amended Complaint against Reckitt Benckiser, Inc., Reckitt Benckiser LLC, Reckitt Benckiser Pharmaceuticals, Inc., Reckitt Benckiser Healthcare (UK) LTD, Reckitt Benckiser Group, PLC, Indivior, Inc., Indivior PLC and Indivior UK Limited as follows:

I. INTRODUCTION

1. This Second Amended Complaint is filed *in camera* and under seal pursuant to 31 U.S.C. §3730(b)(2).

2. This is an action to recover treble damages and civil penalties on behalf of the United States of America, the Commonwealth Of Virginia, the Commonwealth Of Massachusetts, and the states of California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Iowa, Louisiana, Maryland, Michigan, Minnesota, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, Vermont, Washington, Wisconsin, the District Of Columbia, the City of Chicago, the City of New York, the California Department of Insurance and the Illinois Department of Insurance and private insurers in California and Illinois for false claims that were knowingly caused to be presented by the Defendants to certain agencies of the United States, the states and cities listed above, and private insurers in California and Illinois.

3. The false claims complained of herein arise from healthcare services provided under various United States government programs and under the Medicaid and other programs of the states listed in paragraph one, above. This action arises under the provisions of 31 U.S.C. §3729, et seq., commonly known as the False Claims Act (the "FCA") and the related provisions

of state law in effect at relevant times in the states listed in paragraph two and as cited in Counts 1 through 42, herein.

4. The false claims identified herein arise from the manufacture, sale and marketing by the Defendants of two pharmaceuticals, Suboxone and Subutex, which are used in the treatment of opioid addiction and paid for under the following governmental programs: 1) the United States government's Medicare, Medicaid, Railroad Retirement Medicare, CHAMPVA, CHAMPUS, F.A.M.I.S.¹, Tricare, State Legal Immigrant Assistance Grant, Indian Health Service and federal employee and veteran healthcare programs (these programs are sometimes referred to herein as "Federal Payors" or "Federal Payor Programs"); 2) the Medicaid, F.A.M.I.S. and state employee health insurance programs of several states and cities ("State Payors" or "State Payor Programs") including those of the Commonwealth of Virginia, the Commonwealth of Massachusetts and the states of California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Iowa, Louisiana, Maryland, Michigan, Minnesota, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, Vermont, Washington, Wisconsin, the District of Columbia, and the cities of Chicago and New York; and 3) programs paid for by private insurance companies in California and Illinois under the auspices and regulatory requirements of the California Department of Insurance and the Illinois Department of Insurance.

5. The Defendants actively marketed off-label dosages and uses of Suboxone and Subutex. They engaged in unlawful kickback schemes to promote the sales of these drugs and intentionally marketed them to physicians in violation of statutes intended to prevent over prescription and abuse. Perhaps most importantly, when faced with generic competition upon

¹ F.A.M.I.S. is an acronym for Family Access to Medical Insurance Security, a federal program to assist families with healthcare expenses not covered by Medicaid

losing “orphan drug” exclusivity status conferred pursuant to the Orphan Drug Act, Defendants knowingly and falsely marketed Suboxone film, under which they had patent protected rights, as being less vulnerable to diversion and safer than Suboxone tablets. They made these false claims in order to extinguish competition from generic Suboxone tablets.

6. Suboxone achieved sales volume placing it in the top 25 of the world’s top 200 selling pharmaceuticals by dollar volume as of 2010. In 2013, Suboxone achieved approximately \$1.4 billion in annual sales. Annual sales remain over \$1 billion a year as of the filing of this Second Amended Complaint. The damages sustained by the Federal and State Payors as a result of the practices enumerated herein are extraordinarily significant.

II. JURISDICTION AND VENUE

7. The United States District Courts have exclusive jurisdiction over actions brought under the FCA pursuant to 31 U.S.C. §3732, and otherwise have jurisdiction under 28 U.S.C. §§1331 and 1345. This Court has subject matter jurisdiction over the claims brought under the respective state false claims acts identified herein and which are filed under seal pursuant to 31 U.S.C. §3730(b) and 31 U.S.C. §3732(b). This Court also has supplemental jurisdiction over the state and municipal claims pursuant to 28 U.S.C. §1367. At all times relevant hereto, the Defendants regularly conducted substantial business in the Commonwealth of Virginia and maintained and operated sales division offices and certain headquarters in the Commonwealth. Accordingly, the Defendants are subject to personal jurisdiction in the Commonwealth of Virginia. Venue is appropriate in the Western District of Virginia pursuant to 31 U.S.C. §3732(a) and 28 U.S.C. §1391(b)(1) and (2).

8. Section 3732(a) of the FCA provides that “any action under Section 3730 may be brought in any judicial district in which the defendant or, in the case of multiple defendants, any one defendant can be found, resides, transacts business, or in which any act proscribed by

Section 3729 occurred.” The acts complained of herein occurred throughout the United States, the Commonwealth of Virginia and within the geographic area encompassed within the Abingdon Division of the United States District Court for the Western District of Virginia.

9. Under the FCA and the respective state false claims act statutes cited herein, this Complaint is to be filed and remain under seal until the Court orders otherwise.

III. DEFENDANTS

10. Reckitt Benckiser, Inc. (“RBI”) is a Delaware corporation with its principal place of business located at Morris Corporate Center IV, 399 Interpace Parkway, Parsippany, New Jersey 07054. RBI manufactures and sells various products throughout the United States, including pharmaceuticals. RBI was duly authorized to conduct business within the Commonwealth of Virginia at all times relevant to this matter.

11. Reckitt Benckiser, LLC (“RBL”) is a Delaware limited liability company and maintains its principal place of business at Morris Corporate Center IV, 399 Interpace Parkway, Parsippany, New Jersey 07054. RBL manufactures and sells various products, including pharmaceuticals. RBL was duly authorized to conduct business within the Commonwealth of Virginia at all times relevant to this matter.

12. Reckitt Benckiser Pharmaceuticals, Inc. (“RBP”) is a Delaware corporation and maintains its principal place of business at 10710 Midlothian Turnpike, Suite 430, Richmond, Virginia 23235. RBP manufactures and sells, or at times relevant to this Second Amended Complaint manufactured and sold, various products throughout the United States, including pharmaceuticals. RBP was duly authorized to conduct business within the Commonwealth of Virginia at all times relevant to this matter.

13. Reckitt Benckiser Healthcare (UK) Ltd. (“RBH”) is a British corporation incorporated under the laws of England and Wales and maintains its principal office at Dansom

Lane, Hull, North Humberside HU8 7DS, England. RBH manufactures and sells various products throughout the United States and the world, including pharmaceuticals. RBH or its subsidiaries were duly authorized to conduct business within the Commonwealth of Virginia at all times relevant to this matter.

14. Reckitt Benckiser Group, PLC (“RBG”) is a British corporation incorporated under the laws of England and Wales and maintains its principal office at 103-105 Bath Road, Slough, Berkshire, SL1 3UH, England. RBG is a holding company and owns the other Reckitt entities identified herein. It had a market capitalization as of the filing of this Second Amended Complaint of \$49.7 billion and total annual sales of more than \$13 billion. RBG manufactures and sells various products throughout the United States and the world, including pharmaceuticals. RBG or its subsidiaries were duly authorized to conduct business within the Commonwealth of Virginia at all times relevant to this matter. RBG and its subsidiaries, including the other Reckitt entities named herein, manufacture and market branded products for household use, health and personal care, and sell a range of products through over 60 operating companies into nearly 200 countries. The company’s geographical divisions include Europe, North America, Australia and developing markets.

15. RBI, RBL and RBP are operated by, and wholly owned subsidiaries of, RBH and RBG (the terms “Reckitt” and/or “Reckitt Defendant(s)” shall, unless otherwise indicated, include RBI, RBL, RBP, RBH and RBG). The Reckitt Defendants have common ownership, an integrated management structure and their operations and operational plans are intertwined. The managing officers of RBI, RBL and RBP ultimately reported and answered to executives of RBH and RBG at all times relevant to this Complaint.

16. Indivior Inc. is a Delaware corporation having a principal place of business at 10710 Midlothian Turnpike, Suite 430, Richmond, Virginia. Indivior purports to be a wholly owned subsidiary of Indivior PLC, a corporation organized under the laws of England and Wales. Indivior Inc. is a pharmaceutical company that has been engaged in the manufacture, marketing and sale of Suboxone and Subutex since approximately eight months after this suit was originally filed in May of 2013. Indivior, Inc. began operations in approximately January of 2014.

17. Indivior PLC is a public limited company organized under the laws of England and Wales. It maintains its headquarters at 103-105 Bath Road, Slough, United Kingdom. It is a pharmaceutical company that has been engaged in the manufacture, marketing and sale of Suboxone and Subutex since 2014. It is the corporate successor to RBP and was demerged from RBP by actions of RBH and RBG in 2014. It is the corporate parent of Indivior, Inc. It had an initial capitalization of approximately \$3 billion and has current total annual revenue of just over \$1 billion. Indivior PLC's international headquarters shares the same address as the headquarters of RBH and RBG. Immediately after the demerger was effected, the entire RBP management team assumed roles in the service of Indivior identical to those they held at RBP. Relator asserts, upon information and belief, that the sole purpose or primary purpose of the demerger was for the Reckitt Defendants to shed or reduce liability associated with the conduct complained of herein. For this and other reasons, Relator asserts the Indivior entities are the alter ego of, and responsible for the actions of, RBP, and that the Reckitt Defendants remain responsible for the acts of Indivior, Inc., Indivior PLC and Indivior UK Limited.

18. Indivior UK Limited is a public limited company organized under the laws of England and Wales. It was formed in 2014. It maintains its headquarters at 103-105 Bath Road,

Slough, United Kingdom. Upon information and belief, Indivior UK Limited is a wholly owned subsidiary of RBH and/or RBG. Pursuant to the demerger agreement, RBH and Indivior UK Limited entered into a supply agreement executed December 23, 2014, but effective on April 1, 2015. Pursuant to the agreement, RBH manufactures the Suboxone product line exclusively for Indivior UK Limited. In turn, Indivior UK Limited is obligated under this agreement to purchase those products exclusively from RBH for a period of seven (7) years, until 2022, which is the year Suboxone film's patent protection expires. Upon information and belief, Indivior UK Limited is engaged in the distribution of Suboxone and Subutex worldwide.

19. The term "Indivior" shall, unless otherwise indicated herein, mean, jointly and severally, Indivior Inc., Indivior PLC, and Indivior UK Limited. The term "Defendants" shall, unless otherwise indicated, mean, jointly and severally, RBI, RBL, RBP, RBH, RBG, Indivior Inc., Indivior PLC and Indivior UK Limited.

20. The Defendants manufacture and market, or at times relevant hereto manufactured and marketed, various pharmaceuticals subject to approval of the United States Food and Drug Administration ("FDA") and were responsible for the conduct alleged herein.

IV. RELATOR-PLAINTIFF

21. Relator-Plaintiff Ann Marie Williams is a citizen of the United States and the Commonwealth of Virginia. She maintains her principal residence at 3208 St. Stephens Way, Midlothian, Virginia 23113. Williams began employment with RBP in the fall of 2009 in the position of State Government Manager and continued in that position as of the time this suit was originally filed. She has since left RBP. Areas under her supervision included the introduction of Reckitt pharmaceuticals into the various states and obtaining approval of these products from various state Medicaid offices. She has direct knowledge of the facts related herein and is the original source of same. While she is unaware of any of the Counts, fraud allegations and/or acts

described herein having been publicly disclosed as contemplated under 31 U.S.C.

§3730(d)(4)(B), she has made voluntary disclosure of substantially all evidence and information in her possession to authorities responsible for investigating these allegations prior to filing her original Complaint. She has made further substantial disclosures to the United States of additional information that came into her possession after the filing of her original Complaint and of her tape recordings that include conversations of Reckitt executives, district managers, the compliance officer and others making important admissions.

V. FACTS

22. The Defendants knowingly and/or with deliberate indifference made or used false or fraudulent statements and schemes, or caused fraudulent statements to be made and unlawful schemes to be carried out, to obtain, or aid in obtaining, the payment and approval of false claims under Medicare, Medicaid, Railroad Retirement Medicare, CHAMPVA, CHAMPUS, Tricare, State Legal Immigrant Assistance Grant, Indian Health Service, F.A.M.I.S., state employee health insurance and federal employee and veteran health programs. As a result of these false and/or fraudulent statements and schemes, the Federal and State Payors identified herein paid very significant sums of money to the Defendants to which the Defendants were not entitled.

A. Background

23. Defendants manufacture and market or, at times relevant to this Second Amended Complaint manufactured and marketed, Suboxone and Subutex. They are both powerful prescription pharmaceuticals that are used to treat opioid addiction, primarily heroin, methadone, morphine and oxycodone addiction. More specifically, they were originally intended for use in attempting to wean opioid addicts off of these drugs and other opioids or in achieving lower maintenance doses for them. Suboxone is a unique composite drug product consisting of two active pharmacological ingredients, buprenorphine (four parts) and naloxone (one part). Subutex

contains only buprenorphine. A significant number of the patients who are prescribed Suboxone and Subutex are on Medicaid.

24. Buprenorphine provides a maintenance dose of a semi-synthetic opioid which is absorbed through the oral mucosa. Buprenorphine ostensibly has a well-documented “ceiling effect” when taken sublingually which is supposed to make it safer in overdose than other opioids. Defendants marketed these drugs as having a less euphoric effect, being less addictive, being less susceptible to diversion for improper uses, being safer, and having less of a potential for abuse compared to methadone, another drug used to treat opioid addiction. These characteristics ostensibly make it easier and safer to treat addicts and work toward lower doses with a goal of using the lowest optimal dose to avoid withdrawal and craving of opioids.

25. The naloxone contained within Suboxone ostensibly protects the patient from abusing the drug by blocking the action of the buprenorphine and thereby precipitating withdrawal symptoms when the buprenorphine is taken in any manner other than sublingually. According to the Defendants, the protective characteristics of the naloxone will only activate if it is subjected to the addicts’ favored methods of abuse, i.e., dissolved in a solution and injected intravenously or snorted. The naloxone’s blocking effect is ostensibly vitiated in Suboxone when taken sublingually, as directed, because naloxone is poorly absorbed through the oral mucosa. In theory, the combination of compounds in Suboxone allows a safer opioid to be substituted for heroin and the more dangerous opioids while blocking the primary abuse and more dangerous pathways of administration.

26. Naloxone was first approved by the FDA in the 1970’s. Buprenorphine was first approved by the FDA in 1982 as an injectable analgesic. In the 1990’s, Reckitt embarked upon exhaustive research to investigate buprenorphine’s efficacy in the treatment of opioid

dependence. Substantial portions of this research were paid for by grants to Reckitt from the United States National Institutes of Health.

27. When Reckitt introduced Suboxone sublingual tablets in 2002, it was aware that neither Suboxone, its component compounds nor their application in opioid replacement therapy enjoyed patent protection.

28. Reckitt had significant concern about generic competition to Suboxone and engaged an aggressive strategy to prevent that competition. Reckitt sought and obtained from the FDA a seven year period of market exclusivity by having Suboxone categorized as an “orphan drug” under the Orphan Drug Act, 21 U.S.C. §360aa-dd. From the time of Suboxone’s first approval by the FDA in October of 2002 until October of 2009, Reckitt marketed Suboxone tablets free from competition from generic buprenorphine /naloxone. This exclusivity resulted in U.S. sales of over \$1 billion per year. The sales volume of Suboxone reached \$1.4 billion in 2013 and remains over \$1 billion.

29. Suboxone is an expensive drug for the consumer. The profit margins are extraordinarily large even by patent-protected pharmaceutical standards. Thirty tablets in the 8 mg dosage strength had an average wholesale price in early 2011 of \$242.90, over \$8.00 per tablet. The costs of manufacturing and delivering the drug to market does not exceed 10% of its wholesale cost. The patients who are prescribed Suboxone, almost exclusively drug addicts, are poor and often on Medicaid. A significant amount of the purchases are made by the Federal and State Payors identified herein. As a result, generic Suboxone was a particularly attractive market for generic manufacturers.

30. To put the size of this market in perspective, a list of the top 200 selling pharmaceuticals worldwide by dollar volume is attached as **Exhibit A**. Suboxone is number 25.

Suboxone generated more revenue than Viagra, Lunesta, Nasonex, Cialis, Avodart, Enbrel and other well-known and heavily marketed drugs.

31. The extraordinary volume and growth of Suboxone sales illuminate two critical facts: 1) Reckitt's representation in its successful application for "orphan drug exclusivity" that this protection was "necessary" for Reckitt to recover the cost associated with developing the drug for treatment of addicts (most of which studies were paid for by the National Institute of Health) was itself false; and 2) the volume of Suboxone being sold to and consumed by the public exceeds reasonable medical use and constitutes a "red flag" indicating an obvious and very significant level of diversion to improper uses, prescription in dosages which are far too high, and for uses which are inappropriate.

B. Development of Suboxone Film

32. On October 8, 2009, the period of orphan drug exclusivity was scheduled to expire for Suboxone tablets. Reckitt knew that its competitors in the generic market were preparing to manufacture a generic version of the drug.

33. The history of generic drugs in the United States clearly demonstrates that they can present significant, if not lethal, price competition to a brand-name manufacturer. Moreover, the effect of this competition is virtually immediate because of statutes and regulations which in many instances mandate substitution of generics for brand-name drugs. Reckitt was understandably concerned about the competitive market pressure that would be brought to bear when generic Suboxone entered the market.

34. Reckitt developed a plan to thwart competition from generic manufacturers. Approximately two years before the expiration of its orphan drug exclusivity, Reckitt announced to the FDA that it would submit application to manufacture and market a sublingual film version of Suboxone. The application was filed on October 21, 2008.

35. There is no medically-based therapeutic difference between the tablet and the film and there is only a slight difference in bioavailability. As a result, the recommended dosages as between Suboxone tablets and Suboxone film are equivalent. However, the delivery method is materially different. Reckitt knew that Suboxone tablets would not and could not be considered sufficiently similar to branded Suboxone film so as to justify the automatic substitution of less-expensive generic buprenorphine/naloxone tablets when pharmacists were presented with a prescription for the Suboxone film. This automatic substitution of cheaper generics is the regulatory means through which generic competition reduces drug prices for Federal and State Payors.

36. Under Reckitt's plan, if it could introduce its film version of Suboxone into the marketplace, it would cause the market for branded Suboxone tablets to collapse or completely vanish. Accordingly, if the film version of Suboxone became the common means by which patients used the drug then generic Suboxone tablet competition would be avoided and the substantial savings that would otherwise be realized for Suboxone users and the Federal and State Payors would disappear.

37. The FDA raised several objections to the film version of Suboxone. Among its chief concerns were improper diversion, safety and abuse of the film. The FDA had a specific concern regarding the film's safety in households with children. Reckitt specifically represented to the FDA and numerous state agencies and state legislatures that the film version raised no additional or unique safety, abuse or diversion concerns over the drug in the tablet form. In fact, Reckitt falsely represented to these agencies and organizations that the film was safer, less divertible and less vulnerable to abuse than the tablets.

38. Reckitt submitted a risk evaluation and mitigation strategy (“REMS”) after a review of which the FDA approved the film version of Suboxone on August 30, 2010. Reckitt commenced marketing the Suboxone film about that time, although it does not manufacture the film. The film is manufactured for Reckitt by MonoSol Rx, LLC in Warren, New Jersey, which holds a patent on the film, thus rendering Suboxone safe from generic competition for the life of the patent. Introducing a third party manufacturer into its Suboxone production process highlights the lengths to which Reckitt sought to avoid generic tablet competition as the costs of the third party manufacturer reduced the Suboxone profit margin.

39. The new film formulation of Suboxone is actually inferior to Suboxone tablets, and known to Reckitt to be inferior, for many reasons:

i. The film is more susceptible to diversion because it is easy to conceal. Reckitt learned this itself before the film was approved by the FDA when nearly 6,000 strips (46% of those dispensed to study patients) went missing during the clinical studies Reckitt performed in the FDA process. This serves to illuminate the desperation of these patients, the extent of the diversion problem and helps to explain why this drug has a greater sales volume than drugs like Viagra, Nasonex and Enbrel.

ii. Compared to sublingual use of a Suboxone tablet, the film version increases naloxone bioavailability when taken sublingually (this difference in bioavailability does not exist when the Suboxone is dissolved and injected). Accordingly, when used sublingually, the film risks unwanted precipitation of opioid withdrawal, this causes significant induction and stabilization problems at the inception of the patients’ treatment.

iii. The film is much easier to dissolve and inject than the tablet formulation, thus increasing its abuse potential and reducing one of the main benefits Suboxone is supposed to provide.

iv. The film presents substantially increased danger to children because it dissolves rapidly and children who accidentally place Suboxone film in their mouths tend to absorb the buprenorphine it contains dangerously fast. It is difficult or impossible for a child to spit out or remove the film from their mouth because, upon putting it in their mouth, the film hydrates to a gel within approximately 30 seconds and dissolves completely over the course of approximately three minutes releasing all of the buprenorphine. In contrast, Suboxone tablets have a much longer oral residence time and children often spit them out. Moreover, when tablets are swallowed by children, the buprenorphine is absorbed to a far lesser extent compared with the film.

v. The packaging of the film also presents significant safety concerns for children. Each dose of the film is packaged in a child-resistant sleeve. Once the integrity of the sleeve is breached, it no longer offers protection. Reckitt knew that a significant portion of patients took their Suboxone in divided doses, yet supplied no child-resistant bottle or other container into which unused portions of the film could be stored. Suboxone tablets were supplied in a child-proof bottle.

C. Prescription Standards: Permitted “On Label” Uses & DATA 2000 Compliance

40. When Suboxone and Subutex were introduced in their original tablet form, the United States Food and Drug Administration Center for Drug Evaluation and Research reviewed Reckitt’s new drug application (“NDA”) for data and information from clinical trials for the purpose of ensuring that they were appropriate for the asserted uses, dosages and indications. Once Suboxone and Subutex were approved, the FDA worked with Reckitt on the final

publication of the package insert/prescribing information (“Package Insert”) that was to be distributed with the medication. The Package Inserts for Suboxone and Subutex tablets are attached hereto as **Exhibit B**. The Package Insert later approved for Suboxone film is attached as **Exhibit C**.

41. Under the Food, Drug and Cosmetic Act of 1938, pharmaceutical manufacturers are prohibited from “misbranding” or marketing a drug for use in other than FDA approved indications and dosages as set forth in the Package Insert. *See, e.g.*, 29 U.S.C. §331.

42. Suboxone tablets are uncoated and intended for sublingual administration. Suboxone film is also intended for sublingual administration. Both the tablet and the film are available in two dosage strengths: 2 mg buprenorphine with .5 milligrams naloxone; and 8 mg buprenorphine with 2 mg naloxone.

43. Subutex tablets are uncoated and intended for sublingual administration. They are available in two dosage strengths, 2 mg buprenorphine and 8 mg buprenorphine. Subutex contains no naloxone.

44. The Package Insert approved for Suboxone and Subutex tablets by the FDA indicates that they are “indicated for the treatment of opioid dependence.”

45. Under the “**Dosage and Administration**” section of the Package Insert for the tablets it is noted that “Subutex or Suboxone is administered sublingually as a single daily dose in the range of 12-16 mgs/day.”

46. The following guidance is contained under the section of the tablet Package Insert captioned “**Adjusting the dose until the maintenance dose is achieved:**”

The recommended target dose of Suboxone is 16 mg/day. Clinical studies have shown that 16 mg of Subutex or Suboxone is a clinically effective dose compared with placebo and indicate that doses as low as 12 mg may be effective in some patients. The

dosage of Suboxone should be progressively adjusted in increments/decrements of 2 mg or 4 mg to a level that holds the patient in treatment and suppresses opioid withdrawal effects. This is likely to be in the range of 4 to 24 mg/day depending on the individual.

47. An addicts' treating physician must perform a form of diagnosis or assessment known as "induction" before maintenance treatment can begin. During the induction phase the physician determines the appropriate maintenance dosage. Reckitt performed no studies, and no studies were performed by any third parties, assessing Suboxone's efficacy for use in the induction/diagnosis phase of patient assessment. The Package Insert states as follows:

In a one-month study of Suboxone tablets induction was conducted with Subutex tablets. Patients received 8 mg of Subutex on day 1 and 16 mg Subutex on day 2. From day 3 onward, patients received Suboxone tablets at the same buprenorphine dose as day 2. Induction in the studies of buprenorphine solution was accomplished over 3-4 days, depending on the target dose.

48. The tablet Package Insert does not state that Suboxone is appropriate for use during induction.

49. The Package Insert for Suboxone film resolves this issue by noting that "Suboxone film is indicated for the maintenance treatment of opioid dependence" thus making it clear that it is not indicated for induction.

50. The dosage information set forth in the Suboxone film Package Insert is identical to the tablet Package Insert.

51. The Suboxone tablet Package Insert contains a table of "adverse events" by body system and treatment group that were observed during a 16 week study. The study observed and evaluated adverse reactions at various daily dosage levels of Suboxone up to 16 mg. The various dosage levels studied were described as follows:

- i. A 1 mg solution, which would be less than a tablet dose of 2 mg, was described as a “very low” dose;
- ii. A 4 mg solution was noted as approximating a 6 mg tablet and described as a “low dose”;
- iii. An 8 mg solution was noted as approximating a 12 mg tablet and described as a “moderate dose”;
- iv. A 16 mg solution was noted as approximating a 24 mg tablet and was described as a “high dose”.

52. No higher doses were studied for adverse events and, except as noted with a potential 24 mg dose in paragraph 46, *supra*, no higher doses were otherwise noted or contemplated in the Suboxone Package Inserts.

53. The Suboxone Package Inserts for both the film and the tablets note that the drug is indicated for “maintenance treatment of opioid dependence” (Suboxone film) and “treatment of opioid dependence” (Suboxone tablets) “as part of a complete plan to include counseling and psychosocial support.” In order to ensure that physicians monitored the counseling and psychosocial support element of treatment and to stem other potential negative consequences of physicians running Suboxone “mills,” the Drug Addiction and Treatment Act of 2000 (“DATA 2000”) mandated that treating physicians be certified to treat addicts and have no more than 30 patients on Suboxone during their first year of qualification and no more than 100 patients under their supervision on Suboxone after their first year of qualification².

54. Suboxone and Subutex were never approved or indicated for use as a medication for induction, for use in dosages more than 24 mg for use during pregnancy or for treatment of pain by the FDA, and any such uses are off label uses.

² These limits were increased in 2016.

D. Defendants' Fraudulent Practices

55. Defendants' executives, sales representatives and paid physician "treatment advocates" ("TA's"), including but not limited to: Ana Farr (sales representative), Scott Daniel (sales representative), Jaime Neil (sales representative), Joe Hall (sales representative), Clint Gagnon (sales representative), Andie Hall (sales representative), Jessica Burke (sales representative), Mary Bashkar (sales representative), Teri Turconi (sales representative), Melanie Miller (sales representative), Mathew Holland (sales representative), Scott Norman (sales representative), Gina Reed (sales representative), Lori Davis (sales representative), Lori Eaton (sales representative), Stephanie Galicia (sales representative), Jeff Bodenbunrg (sales manager), Jason Boehmer (sales manager), Mike Himple (sales manager), Rosemarie Paulus (sales manager), Michael Bruno (sales manager), James Sharp (executive), Richard Powers (executive), Adrian Norton (executive), Brandy Duso (executive), Vickie Seeger (executive), David Byram (executive), Dr. Jane Ruby (executive), Dr. Mark Crause (TA), Dr. Tom Kosten (TA), Dr. Michael Frost (TA), Dr. Bryan Woods (TA), Dr. Stephen Lamb (TA), Dr. Robin Peavler (TA), Dr. Seth Ivins (TA), Dr. George Bright (TA), Dr. Carl Sullivan (TA) and/or Dr. Bernd A. Wollschlaeger (TA) under the supervision and direction of Shaun Thaxter, former United States CEO and now International CEO, knowingly, with reckless disregard and/or deliberate ignorance as to the truth, falsity and lawfulness of said practices committed the following unlawful acts and fraudulent practices as described in paragraphs 55 through 151, herein³, which include the following:

i. Defendants' sales representatives actively and unlawfully marketed "off-label" dosages of Suboxone over 24 mg per day when the maximum daily dosage indicated in

³ Some of Reckitt's sales representatives, including some of those listed in this paragraph, complained to their area managers that it was an "off label" practice to market Suboxone/Subutex in the manner described in this Complaint. When this would occur, representatives were dissuaded from taking any further action or faced disciplinary action.

the Package Insert and approved by the FDA, was 16-24 mg per day. Defendants' TA's and sales representatives supported this unlawful marketing by providing physicians written detail pieces and oral representations that dosing over 24 mg per day was effective and safe and/or by encouraging physicians that they could prescribe higher dosages by writing the prescriptions for pain (an off label use) rather than addiction.

ii. Defendants' sales representatives unlawfully promoted the off-label use of Suboxone for induction, in both the film and tablet form, when no studies had been performed to evaluate Suboxone's efficacy for induction and in spite of the fact that Suboxone was expressly indicated only for "maintenance treatment" (film) and "treatment" (tablet) for opioid dependence.

iii. Defendants' sales representatives unlawfully promoted the off-label use of Suboxone for use during pregnancy in both the film and tablet form, when no studies had been performed to evaluate Suboxone's efficacy for pregnancy.

iv. Defendants intentionally and unlawfully marketed Suboxone and Subutex to physicians in violation of the Drug Addiction Treatment Act of 2000, 21 U.S.C. §801, et seq. ("DATA 2000") by:

a) knowingly selling, marketing and promoting Suboxone and Subutex to physicians who were not certified and/or registered under DATA 2000;

b) knowingly selling, marketing and promoting Suboxone and Subutex to physicians who had been certified and/or registered under DATA 2000 for less than one year and were treating more than thirty patients in violation of 21 U.S.C. §823(g);

c) knowingly selling, marketing and promoting Suboxone and Subutex to physicians who had been certified and/or registered under DATA 2000 for more than one year and were treating more than 100 patients in violation of 21 U.S.C. §823(g);

d) knowingly selling, marketing and promoting Suboxone and Subutex to physicians to treat additional “addicted” patients over the Data 2000 patient limit; and

e) knowingly selling, marketing and promoting Suboxone and Subutex to physicians by encouraging and persuading them to prescribe higher than approved dosages by writing the prescriptions for pain (an off label use) rather than addiction.

v. Defendants obtained approval of Suboxone film by making false representations to the FDA, and then unlawfully marketing the product to the United States and to multiple states, by knowingly and falsely representing to physicians, State Payors, Federal Payors, state agencies and legislatures that Suboxone film was “safer” for the patients and children than Suboxone tablets;

vi. Defendants obtained approval of Suboxone film by making false representations to the FDA, and then unlawfully marketing the product to the United States and to multiple states, by knowingly and falsely representing to physicians, State Payors, Federal Payors, state agencies and legislatures that Suboxone film had less risk of diversion, misuse and abuse than Suboxone tablets;

vii. Defendants unlawfully paid physicians money ostensibly for providing some educational service to other physicians when, in fact, the physicians were simply being paid to write prescriptions, promote and market Suboxone “off label”, and to falsely promote and market Suboxone film as safer and less divertible than tablets. More specifically, these physicians, many of whom were in Reckitt’s TA program, were paid by Reckitt to market and